PDB28

ECONOMIC EVALUATION OF VILDAGLIPTIN AS ADD-ON THERAPY TO METFORMIN IN DIABETES MELLITUS TREATMENT IN CHINA

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OBJECTIVES: To evaluate the cost effectiveness of vildagliptin compared to pioglitazone and glimepiride when added on to metformin in the treatment of type 2 diabetes mellitus in China. **METHODS:** A Markov model was designed to evaluate the costs and outcomes (life years and QALYs gained) of three different therapies of diabetes mellitus from health insurance perspective. Based on UKPDS Outcomes Model, the model included the following risk engine to simulate complications, including ischemic heart disease, fatal and non-fatal myocardial infarction, heart failure, stroke, blindness, renal failure, amputation, diabetes-related mortality and other deaths. The clinical and quality of life data were obtained from published literature and re-confirmed based on a questionnaire survey from a clinical expert panel of 20 diabetes specialists. The annual cost was calculated based on expert opinions. A probabilistic sensitivity analysis was performed to understand the key drivers and general sensitivity of the model. **RESULTS:** The results showed that compared to the treatment of metformin+pioglitazone and metformin+glimepiride therapy, the add-on of vildagliptin can provide a gain of 0.07 and 0.13 QALYs per patient, respectively. The lifetime cost per patient treated with vildagliptin, pioglitazone and glimepiride added-on to metformin was CNY 124,892 (US$19,824), CNY 134,135 (US$21,291) and CNY 126,010 (US$20,002), respectively. **CONCLUSIONS:** Compared to metformin+pioglitazone and metformin+glimepiride therapies, vildagliptin add-on to metformin therapy improves health outcomes and also leads to cost saving in the treatment of diabetes mellitus in China.

PDB29

COST-EFFECTIVENESS MODELLING OF TYPE-1 DIABETES

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OBJECTIVES: To build a flexible and comprehensive long term Type-1 diabetes model incorporating the most up-to-date methodologies (e.g. capturing parameter uncertainty, time profile of patient characteristics and including patient behaviour) to allow a number of cost-effectiveness evaluations. **METHODS:** An individual patient level discrete event simulation model which includes all the major complications (nephropathy, neuropathy, retinopathy, CVD, PVD, hypoglycaemia, ketoacidosis) and their interactions along with the treatment effects was built based on the developed conceptual model. Patient characteristics (demographics, clinical variables, existing complications and treatment status) are used to estimate the transition probabilities for different events with HbA1c acting as the key variable in the model. Patient behaviour was also incorporated in the cost-effectiveness model by updating HbA1c and other variables in time based on the patient's behaviour. The model was developed in a flexible manner to allow alternative sets of risk equations to be used and the model is being validated for each set of risk equations. Furthermore, the model is capable of performing probabilistic sensitivity analysis allowing us to capture the effects of parameter uncertainty and report the likelihood that interventions are cost-effective. **RESULTS:** A number of cost-effective analyses were performed and the trade-offs between costs and QALYs are presented for different treatment/interventions. **CONCLUSIONS:** The flexible individual patient level discrete event simulation model developed enables cost-effectiveness evaluations of a number of treatments and interventions for Type-1 diabetes. The model allows tracking the history of each of the patients and this enables identification of different sub-groups for targeted interventions. Sensitivity analysis, probabilistic sensitivity analysis and value of information methods will be used to identify the most important parameters in the model.

DIABETES/ENDOCRINE DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PDB30

THE PREVALENCE AND BURDEN OF COMORBID HYPERTENSION AND OBESITY AMONG PATIENTS WITH TYPE 2 DIABETES IN JAPAN

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OBJECTIVES: Although hypertension and obesity are common comorbidities among patients with type 2 diabetes (T2D), their prevalence and burden has often not been explored outside the US. The objective of the current study was to assess the incremental effect of each comorbidity in isolation and in combination among T2D patients in Japan. **METHODS:** Data from the 2010 Japan National Health and Wellness Survey (NHWS) were used in the analysis. The NHWS is an Internet-based self-reported survey administered to the adult population of Japan (N=25,000). Respondents who reported a diagnosis of T2D and provided weight information were included in the analysis; they were subsequently categorized based on their comorbidities: T2D+obesity only, T2D+hypertension only, T2D+obesity+hypertension, or T2D without either obesity or hypertension. Groups were compared on health status (using the SF-12v2) and self-reported health care resource use in the past six months through regression modeling controlling for demographics, health behaviors, and comorbidities. **RESULTS:** Of the 957 patients who reported a diagnosis of T2D, most reported neither an obesity nor hypertension comorbidity (n=506; 52.87%). 255 (26.65%) patients reported T2D+hypertension, 98 (10.24%) reported T2D+obesity, and 98 (10.24%) reported both T2D+hypertension+obesity. Adjusting for demographics, health behaviors, and comorbidities, patients with T2D+obesity (Mean=43.42), T2D+hypertension (Mean=46.51), and T2D+obesity+hypertension (Mean=44.03) all reported significantly worse physical component summary scores than those with only T2D (Mean=47.76) ($p<.05$). Similar, though slightly weaker, differences were observed with respect to health utilities. All comorbidity groups also reported significantly more physician visits (T2D+obesity=14.25; T2D+hypertension=12.06; T2D+hypertension+obesity=15.37) in the past six months compared with those with only T2D (9.94; all ps<.05). **CONCLUSIONS:** Although most patients in Japan with T2D do not have concomitant hypertension or obesity, those that do report a significant health status and direct cost burden. Improved management of these comorbidities could result in a substantial societal benefit.

PDB31

THE PREVALENCE AND BURDEN OF COMORBID HYPERTENSION AND OBESITY AMONG PATIENTS WITH TYPE 2 DIABETES IN URBAN CHINA

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OBJECTIVES: Past research has shown strong associations of hypertension and obesity with type 2 diabetes (T2D); however, most of these studies have been conducted in the US. Given that 92 million patients in China currently have diabetes, the aim of the current study was to assess the prevalence and burden associated with these two comorbidities. **METHODS:** The data source for the current study was the 2010 China National Health and Wellness Survey (NHWS). The NHWS is a self-reported survey administered to the adult population of urban China using a mixed methodology (N=19,954). Only respondents who reported that they had been diagnosed with T2D, and who provided weight information, were included in the analysis. Those with T2D+hypertension only, T2D+obesity only, and T2D+obesity+hypertension were compared with T2D only patients on health status (using the SF-12v2) and self-reported health care resource use in the past six months. Regression modeling controlled for demographics, health behaviors, and comorbidities. **RESULTS:** A total of 552 patients reported a diagnosis of type 2 diabetes with 148 (26.81%) reporting concomitant hypertension, 52 (9.42%) being obese, 43 (7.79%) reporting hypertension and being obese, and 309 (55.98%) having neither comorbidity. Adjusting for demographics, health behaviors, and comorbidities, patients with T2D+hypertension (Mean=42.25), T2D+obesity (Mean=42.29) and T2D+obesity+hypertension (Mean=40.99) all reported significantly worse physical component summary scores than those with only T2D (Mean=44.80) ($p<.05$). All comorbidity groups also reported significantly worse health utilities (T2D+hypertension=0.67; T2D+obesity=0.67; T2D+hypertension+obesity=0.67) compared with those with only T2D (0.71). Similar significant effects were observed for the number of provider visits, emergency room visits, and hospitalizations. **CONCLUSIONS:** Although most patients in urban China with T2D do not have concomitant hypertension or obesity, those that do report a significant health status and direct cost burden. Improved management of T2D and these comorbidities could result in a large societal benefit.

PDB32

OUTCOMES AND PERCEPTIONS OF 4MM PEN NEEDLE USE IN DIABETES PATIENTS: RESULTS FROM A MULTI-CENTER SURVEY PILOT STUDY IN HONG KONG

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OBJECTIVES: A recent study showed that 4mm pen needle (PN) has significantly lowered risk of intramuscular insulin injection and thus reduced risk of hypoglycemia. It is important, however, to understand whether diabetes patients are well adapted to 4mm PN when switched from longer needles. The study is to evaluate the difference in patient perception and outcomes before and after switching to the new 4mm PN. **METHODS:** A prospective pilot survey study was conducted from August 2011 to March 2012 in two public hospitals in Hong Kong. Thirty-four subjects with diabetes on longer PN (8mm, 6mm or 5mm) were randomly selected and consented to switch to 4mm PN for two to four weeks. Questionnaires included perception and outcomes Five-point Likert scales were employed to measure pain level, satisfaction level, insulin leakage, injection pressure, and ease of injection to different body areas pre- and post- switch of longer to shorter PN. Insulin leakage volume pre- and post switch was compared using a droplet size chart representing 1uL, 10uL, 20uL, and 40uL. Statistical analyses were conducted using SAS (v9.1). **RESULTS:** The overall response rate was 94.1% (N=32). Demographics of respondents: 48.9±18.6 years (13-76 years); 64.5% females; 46.7% T1DM; A1C: 8.7±1.7% (5.7-12.7%); BMI: 24.0±45.1kg/ m^2 (17.5-40.0kg/m^2); average insulin dosage: 46.9±18.6U (6-86U). Of all analyzed, 33.3% generally injected with high speed to avoid pain. There was no significant difference in the volume of insulin leakage pre- and post PN switch when injecting on abdomen (p= 0.7530) or thigh (p=0.5637); no significant difference in level of pain (p=0.0519). **CONCLUSIONS:** The use of 4mm PN showed no difference in outcomes and perception of use when switched from 8, 6, 5 mm PN in a heterogeneous sample with obese, overweight, normal and skinny patients. A tendency of preference towards 4mm PN with lower pain level and less leakage may be observed with larger sample size.

PDB33

PHYSICIAN'S AND PATIENT'S PERCEPTIONS AND BELIEFS REGARDING INSULIN INITIATION AND USE IN PATIENTS WITH TYPE 2 DIABETES (T2DM) IN CHINA

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OBJECTIVES: To explore physician's and patient's perceptions of insulin initiation and use in patients with T2DM in China. **METHODS:** This study used the 2008 Adelphi T2DM Disease Specific Programme©, a cross-sectional study of consulting physicians and patients providing insights into 'real-world' behaviours and atti-

tudes in clinical practice. Data was collected on 1648 patients with T2DM receiving at least one oral anti-diabetic with/without insulin and 141 specialists and 59 internal medicine physicians in 9 Chinese cities, through physician interviews, patient record forms, and self-completed questionnaires. **RESULTS:** Among the 200 physicians in the study, the most frequently reported concerns with starting insulin were patient's acceptance and ability to comply in the long-term (91.9% of respondents), and the long time needed to train on injection techniques and dosing (74.0%). Forty-three percent of physicians believe patients fear injections, but a higher percentage of patients (55.3%) report not liking injections. Thirty-seven percent of physicians believe social stigma is a barrier; only about 17.1% of insulin-naive patients believe so. Among 474 insulin-naive patients, the most frequently reported concern was that starting insulin would mean their diabetes is at an advanced stage (67.5% of respondents). Physicians underestimate that concern, with only 30% reporting that as a barrier. Almost half of insulin-naive patients (45.1%) would consider insulin initiation as a personal failure to control their diabetes. Among 346 patients taking insulin, 60.1% reported feeling better and 55.7% felt a more positive outlook since starting insulin; 59.8% thought insulin made their diabetes easier to manage. **CONCLUSIONS:** Physicians in China may over or underestimate patient perceived barriers to, and satisfaction with, insulin initiation. Physician/patient education focused on perceived barriers to insulin initiation, and patient/physician communication may facilitate the initiation of insulin in patients with this progressive disease. Interventions to address system-level barriers, e.g. time for training, are warranted.

PDB34

IMPROVEMENTS IN QUALITY OF LIFE ASSOCIATED WITH BIPHASIC INSULIN ASPART 30 IN TYPE 2 DIABETES PATIENTS IN CHINA: RESULTS FROM THE A1CHIEVE OBSERVATIONAL STUDY

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OBJECTIVES: To examine the effects on the health-related quality of life (HRQoL) after starting insulin with, or switching to, biphasic insulin aspart 30 (BIAsp30) in Chinese subjects with type 2 diabetes (T2DM) in the A_1chieve study. **METHODS:** The A_1chieve study was a 24-week, prospective, non-interventional, observational study conducted in routine clinical practices in 28 countries. In China, there were 8,578 T2DM patients recruited from 131 hospitals into the BIAsp30 treatment group (starting insulin with or switching to BIAsp30 at baseline based on physicians' clinical judgments). HRQoL was assessed at baseline and 24 weeks by the validated EQ-5D questionnaire (five dimensions and visual analogue scale (VAS)). Descriptive statistics, paired t-test, and chi-square were conducted for the analyses. **RESULTS:** The mean age of patients (±SD) was 54.9±14.4 years. 57% were male. The reported HRQoL as measured by VAS score (on a scale of 0-100) increased by 6.2 from 75.8 to 82.0 for the overall cohort ($p<0.001$). For insulin naïve patients, starting insulin with BIAsp30 was associated with a 6.1 increase in VAS score from 75.9 to 82.0 ($p<0.001$). Similarly, for insulin experienced patients, switching to BIAsp30 was associated with a 6.7 increase in VAS score from 75.3 to 82.0 ($p<0.001$). For the overall cohort in the five dimensions of EQ-5D, the percentage of patients reported no problems in walking increased from 88.4% to 91.4% ($p<0.0001$) after 24 weeks. Similarly, the percentage of patients reported no pain or discomfort increased from 77.3% to 82.8% ($p<0.0001$), reported not anxious or depressed increased from 74.2% to 77.1% ($p<0.001$). The percentage of patients reported no problems in self-care and usual activity only slightly reduced (-0.2%, -0.5%, respectively) with no statistical significance. **CONCLUSIONS:** Starting insulin with, or switching to, BIAsp30 were associated with significant HRQoL improvement in Chinese T2DM subjects of the A_1chieve study.

PDB35

VALIDATION OF THE PROBLEM AREAS IN DIABETES QUESTIONNAIRE AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS IN SINGAPORE: A PILOT STUDY

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Psychological distress often occurs in patients with diabetes, resulting in poorer therapeutic outcomes. The Problem Areas in Diabetes (PAID) questionnaire covers frequently reported diabetes related emotional problems. Utilizing PAID to identify distressed diabetic patients would be beneficial. **OBJECTIVES:** PAID was originally developed for the American population. Cross-cultural differences in health perceptions are well documented; thus it is necessary to verify the validity and reliability of PAID in Singapore. Design: Cross-sectional study. PARTICIPANTS: Patients with Type 2 diabetes, 21-65 years old, English-speaking, without obvious cognitive impairment and visited the Diabetes Clinic at National University Hospital. **METHODS:** Validity of the scale was evaluated by factor analysis, known group (defined by socio-demographics and clinical variables), convergent/divergent and concurrent validity. Reliability (internal consistency) was evaluated by Cronbach's alpha. **RESULTS:** Exploratory factor analysis revealed three factors. All items loaded onto one factor (distress related problems). A few items loaded onto multiple factors. PAID scores were significantly higher in patients with HbA1c 7.5% ($p=0.02$) and living in HDB 5-room or smaller flats ($p=0.01$), supporting known group validity. Other hypothesized known group differences were not observed. PAID correlated significantly with Kessler10 (K10) and World Health Organization Quality of Life (WHOQOL-BREF), thus demonstrating convergent and concurrent validity. PAID correlated weakly with WHOQOL-BREF's physical domain, thus demonstrating divergent validity. Internal consistency was high (Cronbach's alpha=0.96). **CONCLUSIONS:** PAID is a valid and reliable scale to evaluate diabetes-related emotional distress in the Singaporean Type 2 diabetes population. Further evidence on known group validity needs to be accumulated in future studies.

PDB36

GLYCEMIC CONTROL AND QUALITY OF LIFE FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS IN CHINA

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OBJECTIVES: To examine the association between glycemic control and quality of life (QoL) among patients with type 2 diabetes mellitus (T2DM) in China. **METHODS:** Data were obtained from a cross-sectional survey of T2DM patients in outpatient settings from October to December 2011 in Beijing and Tianjin. Eligible patients were ≥18 years, had a diagnosis of T2DM ≥1 year and received ≥1 year anti-diabetic treatment at the time of survey. EQ-5D index score and visual analog scale (VAS) score were calculated for all T2DM patients and compared between subgroups defined by fasting blood glucose control (FBG<8 mmol/L) and 2-hour post-prandial glucose control (2h-BG<10 mmol/L). Multivariate linear regression models were applied to assess the associations between glucose control and patient QoL, adjusting for age, gender, BMI, weight gain, education and life style (including smoking, drinking and exercise). **RESULTS:** A total of 500 patients with T2DM were included in the analysis with 54.6% female, mean age of 63.2 years and mean disease duration of 11.5 years. Among them, 64.6% reported FBG<8mmol/L and 45.6% reported 2h-BG<10mmol/L based on the last test in the past 2 weeks. Mean EQ-5D and VAS scores for all patients were 0.78 and 68.25, respectively. Compared with patients without FBG control, patients with FBG control had significantly higher EQ-5D (0.80 vs. 0.75, P=0.005) and VAS scores (69.40 vs. 66.16, P=0.017). Similarly, patients with 2h-BG control had significantly higher scores than those without 2h-BG control (0.82 vs. 0.75 for EQ-5D; 71.82 vs. 65.26 for VAS, both P<0.001). The regression analysis showed that 2h-BG control, but not FBG control, was significantly associated with higher EQ-5D (P=0.035) and VAS scores (P=0.000). Older age, less education, weight gain and less exercise were also significantly associated with lower QoL. **CONCLUSIONS:** Better glycemic control at 2-hour post-prandial is associated with improved QoL in patients with T2DM.

INFECTION - Clinical Outcomes Studies

PIN1

EFFICACY AND SAFETY OF TENOFOVIR AS COMPARED WITH ALTERNATIVE TREATMENT OPTIONS FOR NAIVE CHRONIC HEPATITIS B – A SYSTEMATIC REVIEW AND MIXED TREATMENT COMPARISON

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OBJECTIVES: To assess efficacy and safety of tenofovir (TDF) as compared with other nucleot(s)ide analogues (NAs) and peginterferon alpha 2a (PegIFNα2a) for naive chronic hepatitis B. **METHODS:** Comparison was based on randomized controlled trials (RCTs) identified by means of systematic review, carried out according to the Cochrane Collaboration guidelines. Studies met the inclusion criteria if they directly compared at least two of the following interventions: TDF, PegIFNα2a ETV, ADV, LAM or placebo. The most important medical databases (MEDLINE, CENTRAL, EMBASE) were searched until February 2012. Two reviewers independently selected trials, assessed their quality and extracted data. Mixed treatment comparison (MTC) was performed using WinBugs software. Subgroup analysis was performed according hepatitis B antigen e status. **RESULTS:** We identified 20 relevant studies. The results of MTC showed that in app. one year of follow up TDF significantly increased the odds of HBV DNA clearance when compared with PegIFNα2a (OR = 66.22 [5.98; 733.54]); ETV (OR = 8.45 [1.12; 63.98]); ADV (OR = 13.04 [3.62; 46.94]) and LAM (OR = 41.72 [5.27; 330.54]). TDF was superior than PegIFNα2a with respect to ALT normalization (OR = 3.07 [1.04; 9.09]) but did not differ significantly from other NAs. Percentage of patients with any adverse events was significantly lower in TDF group when compared with PegIFNα2a (OR = 0.19 [0.07; 0.48]), while no differences were found between TDF and placebo as well as other NAs with respect to the safety profile. The rates of ALT flares were similar in all treatments arms. In contrast to other NAs there were no resistance to TDF through five years. **CONCLUSIONS:** TDF demonstrated the highest efficacy with respect to the reduction of viral load in treatment naïve patients with chronic HBV and maintained a very good safety profile.

PIN2

ASSESSING THE DIAGNOSTIC PERFORMANCE OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1) TROPISM TESTING METHODS: A SYSTEMATIC REVIEW OF GENOTYPIC SEQUENCING OF THE THIRD HYPERVARIABLE (V3) LOOP AND ENHANCED-SENSITIVITY PHENOTYPIC ASSAY TECHNOLOGY

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OBJECTIVES: To evaluate the relative diagnostic performance of genotypic sequencing and enhanced-sensitivity phenotypic testing methods for: i) identifying the tropism of HIV-1 infected patients, and ii) predicting virological response to CCR5-antagonist therapy. **METHODS:** A systematic review of the literature (via EMBASE and Medline databases) initially identified 359 publications. Based on *a priori* defined eligibility criteria, five studies were included in the final analysis. **RESULTS:** Four of the five studies assessed the diagnostic performance of genotypic testing in identifying viral tropism, with the enhanced-sensitivity Trofile assay (ESTA) as the reference standard. Using the geno2pheno bioinformatic algorithm, genotypic testing maintained a high concordance with ESTA (range: 70.6%-85.3%).